REMARKS

Claims 7 and 38-54 are pending. Applicants have amended Claims 39-42 to correct a typographical error. As such, the amendments add no new matter. Claims 7 and 38-54 stand rejected by the Examiner. Applicants respond below to the rejections set forth in the Office Action mailed September 29, 2006. For the reasons set forth below, Applicants respectfully traverse.

Rejection Under 35 U.S.C. § 102(e)/103(a) - The'129 Patent

The Examiner has maintained the rejection of Claims 7, 38, 39, 41, 44-49 and 53 under 35 U.S.C. § 102(e), or alternatively 35 U.S.C. § 103(a) as allegedly being anticipated by or obvious over the '129 patent for the reasons set forth in the previous office action. According to the Examiner, the '129 patent discloses a method of treating high LDL and triglycerides by administering a composition containing an amount of biotin and an amount of chromium glycinate that fall within the scope of the rejected claims, thereby expressly or inherently teaching all of the limitations of the rejected claims. Applicants respectfully traverse.

As discussed during the interview of March 1, 2007, Applicants intended meaning of the phrase "consisting essentially of" in the claims excludes several of the ingredients present in the composition of the '129 patent. Specifically, Applicants' claims exclude the administration of bioactive ingredients that affect serum HDL, LDL and triglyceride levels, such as L-carnitine, ascorbic acid, and L-arginine. As agreed during the interview on March 1, 2007, the Examiner will clarify the meaning of "consisting essentially of," in the reasons for allowance. Accordingly, as agreed during the interview, the '129 patent does not teach or suggest the methods claimed by Applicants. Applicants respectfully request that the Examiner withdraw the rejections under 35 U.S.C. § 102(e)/103(a) over the '129 patent as was agreed upon during the interview.

Rejection Under 35 U.S.C. § 102(b) - The '066 Patent

The Examiner has rejected Claims 7, 38-50, 53 and 54 under 35 U.S.C. § 102(b)/103(a) as allegedly being anticipated by, or alternatively obvious over the '066 patent for the reasons set forth in the previous Office Action. Briefly, the Examiner maintains his position that reducing hyperglycemia and stabilizing serum glucose levels as disclosed in the '066 patent will inherently treat dyslipidemia and increase HDL cholesterol levels.

During the interview on March 1, 2007, Applicants discussed the differences in the methods disclosed in the '066 patent and claimed in the instant application. Specifically, Applicants explained that not all individuals with hyperglycemia also have dyslipidemia and that not all individuals with dyslipidemia also have hyperglycemia. While some overlap may exist between the population of individuals with hyperglycemia or unstable serum glucose levels and the population of individuals with dyslipidemia, the two populations are not the same. As explained by Applicants, while individuals may present with both conditions, contrary to the Examiner's assertions in the Office Actions, there is no established causal relationship between diabetes and dyslipidemia, and thus there is not a one-to-one relationship between hyperglycemia and dyslipidemia. The administration of chromium and biotin in an individual in need of stabilization of serum glucose levels or treatment of hyperglycemia is not necessarily and always the same as the administration of chromium and biotin to an individual in need of treatment of dyslipidemia. As such, the '066 patent does not expressly or inherently teach each and every limitation of Claims 7, 38-50, 53 and 54, and cannot be anticipatory under 35 U.S.C. § 102. Applicants thus respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 102(b), as agreed upon during the interview.

Rejection Under 35 U.S.C. § 103(a) - The '066 Patent, '401 Patent, '772 Patent, '615 Patent, '129 Patent and '304 Patent

The Examiner has maintained the rejection of Claims 7 and 38-54 allegedly being obvious over the '401 patent or the '066 patent in view of U.S. Patent 5,948,772 to de la Harpe et al. ("the '772 patent"), U.S. Patent No. 5,194,615 to Jensen et al. ("the '615 patent"), the '129 patent and U.S. Patent No. 6,140,304 to Sears ("the '304 patent").

However, none of the cited references, alone or in combination, teach or fairly suggest each and every element of the claimed invention. As discussed above in the rejection under 35 U.S.C. § 102(b), there is no established causal relationship between hyperglycemia and dyslipidemia, as discussed and agreed upon during the interview of March 1, 2007. As such, neither the '066 patent nor the '401 patent discloses methods of treating dyslipidemia in individuals in need thereof as recited in the claims. The teachings of the other cited references, alone and in combination with the '401 and the '066 patents fail to provide the requisite disclosure necessary to support the rejection under 35 U.S.C. § 103(a). Specifically, as discussed

below, none of the cited references teaches that a composition consisting essentially of chromium and biotin is useful for treating dyslipidemia.

The Examiner relies upon the '304 patent for the proposition that insulin resistance is commonly associated with increased triglycerides, decreased HDL cholesterol, and elevated body fat. As discussed during the interview, there is no established, causal relationship between type II diabetes and lowered serum HDL levels. In fact, as explained by Applicants during the March 1, 2007 interview, the mechanism underlying dyslipidemia is unclear. If treating hyperglycemia and stabilizing serum glucose levels in any individual, *e.g.*, individuals with Type II diabetes, also always treated dyslipidemia as suggested by the Examiner, and a causal relationship between the conditions existed, then the skilled artisan would expect that any composition useful in reducing hyperglycemia and stabilizing serum glucose would treat dyslipidemia. Applicants' previously provided evidence in the Submission with Request for Continued Examination mailed June 7, 2006 demonstrates that some of the most commonly used drugs to treat hyperglycemia worsen individuals' lipid profiles. Declaration of James Komorowski Under 37 C.F.R. § 1.132 at ¶¶8-12. Because hyperglycemia and dyslipidemia are independent, often unrelated disorders, the skilled artisan would not reasonably expect that the combination of chromium and biotin would be useful in the treatment of dyslipidemia. Thus, the skilled artisan would not be motivated to administer the combination of chromium and biotin to an individual in need of treatment for dyslipidemia.

The Examiner relies on the disclosures of the '772 patent and the '615 patent as evidence that chromium and chromium complexes were known to have beneficial effects on triglyceride levels, LDL cholesterol levels, and HDL cholesterol levels. These references relate to uses of chromium supplements, however, and are silent regarding any biological activity that biotin may have on lipid profiles, either alone or in combination with chromium. Applicants' claimed invention is based on the unexpected synergistic beneficial effect that the *combination* of chromium and biotin exhibit on serum lipid profiles. Nothing in the '772 patent or the '615 patent suggests that combining biotin with chromium would have the unexpected, synergistic effects on lipid profiles demonstrated by Applicants and recited in Applicants' claims. *See, e.g., Specification* at Figures 13 and 14. Figures 13 and 14 demonstrate that the combination of chromium and biotin, at both low and high doses has a synergistic, beneficial effect on

cholesterol profiles. As is the case with the '304 patent, the skilled artisan would thus not be motivated to administer the combination of chromium and biotin to an individual in need of treatment for dyslipidemia in view of the teachings of the '772 patent and the '615 patent, alone or in combination with either the '401 or the '066 patent.

The Examiner argues that Applicants' evidence of synergy is not commensurate in scope with the breadth of the claims. As agreed upon during the interview, Applicants' provide herewith a Declaration attesting to the actual amounts of chromium and biotin used in the experiments depicted in Figures 13 and 14. Paragraph 3 of the Declaration states that "Low Chromium" or "LC" treatments were 1μg Cr/kg, *i.e.*, approximately 60 μg chromium per day for an average individual. "High Chromium" or "HC" treatments were 10μg Cr/kg, *i.e.*, approximately 600 μg chromium per day for an average individual. "Low Biotin" or "LB" treatments were 30μg biotin/kg, *i.e.*, approximately 1,800 μg biotin per day for an average individual. "High Biotin" or "HB" treatments were 300μg biotin/kg, *i.e.*, approximately 18,000 μg biotin per day for an average individual. Thus, contrary to the Examiner's assertions, Applicants' recitation of the claimed synergistic amounts of chromium and biotin are fully supported by the data shown in Figures 13 and 14, and elsewhere throughout the specification.

Finally, according to the Examiner, the '129 patent describes improvement in triglyceride levels and LDL cholesterol levels using a composition that comprises chromium glycinate and biotin. As previously discussed, the composition in the '129 patent discloses a multivitamin that contains more than thirty-five compounds. Applicants have provided evidence that many of the compounds in the '129 multivitamin are known to have an effect on serum lipid levels. *See,* Response to Office Action mailed November 28, 2005 and references and exhibits cited therein. Applicants maintain that compounds affecting the basic and novel characteristics of Applicants' claimed invention are excluded by Applicants' claims, which recite the transitional phrase "consisting essentially of." As indicated in the Summary of Interview, the undersigned and the Examiner agreed that the Examiner would include a statement in the Notice of Allowance that the meaning of "consisting essentially of" as recited in Applicants' claims functions to exclude bioactive compounds that affect serum lipid levels.

Applicants respectfully submit that in view of the above, the cited references do not support the rejection under 35 U.S.C. § 103(a) maintained in the instant Office Action.

Applicants accordingly respectfully request that the Examiner withdraw the rejection of Claims 7 and 38-54, as agreed upon during the March 1, 2007 interview.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully maintain that the claims are patentable and request that they be passed to issue. Applicants invite the Examiner to call the undersigned if any remaining issues may be resolved by telephone.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 15 March 2007

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